

WE CLAIM AS OUR INVENTION:

1. An intracorneal insert for introduction into the cornea of a human eye, said insert comprising a physiologically compatible material and being adapted for implantation within a human cornea, said insert having a radius of curvature, measured along its centroidal axis, of at least 5.0 mm.

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2. The insert of claim 1 wherein said radius of curvature is at least 5.5mm.

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3. The insert of claim 1 wherein said radius of curvature is from 6.0 to 9.0 mm.

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4. The insert of claim 1 wherein said radius of curvature is from 7.0 to 8.0mm.

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5. The insert of claim 1 wherein said radius of curvature approximates a human corneal curvature along a corneal meridian.

6. The insert of claim 1 where said insert comprises a low modulus physiologically compatible polymer.

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7. The insert of claim 6 wherein the low modulus physiologically compatible polymer is selected from polyhydroxyethylmethacrylate, polyvinylpyrrolidone, polyethylene oxide, or polyacrylates, polyacrylic acid and its derivatives, their copolymers and interpolymers, silicones, crosslinked dextran, crosslinked heparin, or crosslinked hyaluronic acid.

8. The insert of claim 7 wherein the low modulus physiologically compatible polymer is selected from polyhydroxyethylmethacrylate and polyvinylpyrrolidone.

5 9. The insert of claim 6 wherein the low modulus physiologically compatible polymer is selected from hydratable polymers which swell upon hydration, hydratable polymer systems which do not swell upon hydration, and elastomers.

10 10. The insert of claim 6 wherein the low modulus, physiologically compatible polymer comprises an elastomer.

15 11. The insert of claim 1 where said insert comprises a polymer having a high modulus of elasticity.

12. The insert of claim 11 wherein the polymer is selected from polymethylmethacrylate; fluorocarbon resins; polysulfones; polycarbonate; epoxies; and polyolefins selected from polyethylene, polypropylene and polybutylene.

20 13. The insert of claim 12 wherein the polymer comprises polymethylmethacrylate.

14. The insert of claim 1 having a hollow inner portion.

25 15. The insert of claim 14 wherein the hollow inner portion is filled with a liquid.

16. The insert of claim 15 wherein the hollow inner portion is at least 30 partially filled with a gel or a settable polymer.

5 17. The insert of claim 16 wherein the gel or settable polymer is selected from polyhydroxyethylmethacrylate hydrogel, cross-linked collagen, cross-linked hyaluronic acid, siloxane gels, polyvinyl pyrrolidone, and organic-siloxane gels.

10 18. The insert of claim 17 wherein the gel or settable polymer is polyvinyl pyrrolidone.

15 19. The insert of claim 14 wherein the hollow portion is at least partially filled with a drug or biologic agent.

20 20. The insert of claim 19 wherein the drug is selected from dexamethasone, heparin, corticosteroids, antimitotics, antifibrotics, anti-inflammatory, anti-scar-forming, anti-adhesion, antithrombogenic, and antiangiogenesis factors.

25 21. The insert of claim 20 wherein the drug is an anti-inflammatory or antithrombogenic.

20 22. The insert of claim 6 additionally comprising a drug or biologic agent.

25 23. The insert of claim 22 wherein the drug is selected from dexamethasone, heparin, corticosteroids, antimitotics, antifibrotics, antiinflammatories, anti-scar-forming, anti-adhesion, antithrombogenic, and antiangiogenesis factors.

24. The insert of claim 23 comprising an anti-inflammatory or antithrombogenic.

25. The insert of claim 1 additionally comprising an ocular lubricant.

5 26. The insert of claim 25 wherein the ocular lubricant is selected from hyaluronic acid, methylethylcellulose, dextran solutions, glycerine solutions, polysaccharides, or oligosaccharides.

10 27. The insert of claim 1 comprising at least two polymeric layers.

28. The insert of claim 27 wherein at least one polymeric layer comprises a low modulus physiologically compatible polymer. *initial*

15 29. The insert of claim 27 wherein at least one polymeric layer comprises a high modulus physiologically compatible polymer. *initial*

30. The insert of claim 1 wherein the insert includes a portion having a length to width ratio of at least 1:1.

20 31. The insert of claim 1 having a predetermined shape.

32. The insert of claim 1 being constructed to substantially retain its shape over time after implantation within the cornea.

25 33. The insert of claim 1 being configured and adapted to alter the topography of the cornea in a manner that effects correction of a predetermined refractive disorder of the eye.

34. The insert of claim 1 being configured and adapted to alter the shape of the cornea by a predetermined amount.

35. The insert of claim 1 wherein said insert is radially arcuate.

36. An intracorneal insert for introduction into the cornea of a human eye, said insert comprising a physiologically compatible material and being adapted for implantation within a human cornea, said insert being without curvature along its centroidal axis

5 37. The insert of claim 36 being configured and adapted to alter the topography of the cornea in a manner that effects correction of a predetermined refractive disorder of the eye.

10 38. The insert of claim 36 being configured and adapted to alter the shape of the cornea by a predetermined amount.

15 39. The insert of claim 36 having a predetermined shape.

40. The insert of claim 36 being constructed to substantially retain its shape.

20 41. An intracorneal insert for introduction into the cornea of a human eye, said insert comprising a physiologically compatible material and being configured and adapted for implantation within a human cornea, said insert having a length measured along its centroidal axis of less than or equal to 2.5 mm.

25 42. The insert of claim 41 being configured and adapted to alter the topography of the cornea in a manner that effects correction of a predetermined refractive disorder of the eye.

30 43. The insert of claim 41 being configured and adapted to alter the shape of the cornea by a predetermined amount.

44. The insert of claim 41 having a predetermined shape.

45. The insert of claim 41 being constructed to substantially retain its
5 shape.

46. The insert of claim 41 wherein said insert has a radius of curvature,
measured along its centroidal axis, of at least 5.0 mm.

10 47. The insert of claim 46 wherein said radius of curvature is from 6.0
to 9.0 mm.

48. The insert of claim 46 wherein said radius of curvature is from 7.0
to 8.0 mm.

15 49. The insert of claim 41 wherein said length is less than or equal to
2.0 mm.

20 50. A procedure for introducing an intrastromal insert into a cornea of
a mammalian eye comprising the steps of:
a) making an initial incision in or near the cornea; and
b) introducing a biocompatible radially arcuate insert
comprising a physiologically compatible polymeric segment through said initial
incision in a direction along a meridian of the cornea.

25 51. The procedure of claim 50 wherein the initial incision is along a
circumference of the cornea.

30 52. The procedure of claim 50 wherein the initial incision is along a
meridian of the cornea.

53. The procedure of claim 50 wherein the initial incision is in the sclera of the eye.

5 54. The procedure of claim 50 comprising the additional step of producing an intrastromal intracorneal channel in the cornea from the initial incision prior to introducing the biocompatible radially arcuate insert into said initial incision.

10 55. The procedure of claim 50 comprising the additional step of producing at least one additional incision in said cornea for introducing at least one additional biocompatible radially arcuate insert into said cornea.

15 56. The procedure of claim 50 comprising the additional step of introducing at least one additional radial insert into said at least one additional incision.

20 ✓57. A procedure for introducing a biocompatible gel into a cornea of a mammalian eye comprising the steps of:

a) making an initial incision in or near the cornea; and
b) introducing a biocompatible gel through said initial incision in a direction along a meridian of the cornea.

25 58. The procedure of claim 45 wherein the initial incision is along a circumference of the cornea.

59. The procedure of claim 45 wherein the initial incision is along a meridian of the cornea.

60. The procedure of claim 45 wherein the initial incision is in the
sclera of the eye.

5 61. The procedure of claim 57 comprising the additional step of
producing an intrastromal intracorneal channel in the cornea from the initial
incision prior to introducing the biocompatible radially arcuate insert into said
initial incision.

10 62. The procedure of claim 57 comprising the additional step of
producing at least one additional incision in said cornea for introducing at least
one additional biocompatible radially arcuate insert into said cornea.

15 63. The procedure of claim 57 wherein the gel is selected from the
group consisting of polyhydroxyethylmethacrylate hydrogel, cross-linked
collagen, cross-linked hyaluronic acid, polyvinylpyrrolidone, polyacrylonitriles,
polyacrylamides and polyacrylic acids.

20 64. The procedure of claim 57 comprising the additional step of
forming a pocket in a direction along a meridian of the cornea from said incision.

65. An intracorneal insert for introduction into the cornea of a human
eye, said insert comprising a physiologically compatible material and being
adapted for implantation within a human cornea, said insert having a first
elongated portion and a second elongated portion extending therefrom.

25 66. The insert of claim 65 wherein said first elongated portion has a
second and a third elongated portion extending therefrom.

67. An intracorneal insert for introduction into the cornea of a human
eye, said insert comprising a physiologically compatible material and being

adapted for implantation within a human cornea, said insert having a boomerang shape.

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